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Inventors:	**Natarajan Ranganathan**
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Title:	**Nutritional Compositions Comprising Probiotics**

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I hereby certify that this paper is being electronically submitted on the date indicated above to the Commissioner for Patents, U.S. Patent & Trademark Office (AF).

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Commissioner for Patents
U.S. Patent & Trademark Office
(AF)

APPEAL BRIEF

TABLE OF CONTENTS

I. Real Party in Interest

The real party in interest is Kibow Biotech, Inc.

II. Related Appeals and Interferences

There are no related appeals or interferences.

III. Status of Claims

Claims 1-10 are pending in this application.

Claim 11 has been canceled.

Claims 1-10 have been rejected and are on appeal.

A claim appendix including the text of the appealed claims is attached.

IV. Status of Amendments

The response to the Final Office Action filed on November 28, 2007 was entered upon filing of this appeal. However, a December 20, 2007 Advisory Action indicated that the rejections were maintained.

V. Summary of the Claimed Subject Matter

Claim 1 defines a nutritional food or nutritional product containing a significant titer of viable probiotic bacteria for maintaining or enhancing gastrointestinal health. The claimed nutritional food or nutritional product is composed of at least one probiotic bacterium, at least one carbohydrate, at least one fat ingredient, and at least one protein ingredient. See page 4, lines 26-29, of the specification. In particular, the probiotic bacterium, *Streptococcus thermophilus*, is selected for use in the nutritional food or nutritional product because of its propensity to hydrolyze nitrogenous wastes, wherein 5 billion to 20 billion colony forming units achieve a beneficial effect. See page 6 (lines 12-19), page 7 (lines 2-4), the paragraph spanning pages 8 and 9, page 11 (lines 11-16), page 13 (lines 22-28), and page 18 (lines 29-31). The carbohydrate ingredient is included at about 47% to about 82% by weight of the total weight of the nutritional food or nutritional product. See page 5 (lines 19-14), page 15 (lines 12-24), and page 16 (lines 15-17). Similarly, the protein ingredient is included at a range of from about 5% to about 80% by weight of the total weight of the nutritional food or nutritional product. See the paragraph spanning pages 5 and 6 and the passage at page 17, lines 9-24. At least one fat ingredient is incorporated at about 2% to about 12% by weight of the total weight of the nutritional food or nutritional product to provide the added benefit of protecting the probiotic bacteria from moisture and maintaining viability. See page 5 (lines 25-29) and page 16 (lines 24-26). Moreover, a water activity of less than about 0.47 is specified to maintain viability of the probiotic bacteria and increase shelf-life of the nutritional food or nutritional product. See the paragraph spanning pages 12 and 13, page 14 (lines 14-24), and page 19 (lines 11-17).

Claim 2 defines additional probiotic bacteria which can be included in the nutritional food or nutritional product. Such

probiotic bacteria are selected from various species of *Lactobacillus*, *Bacillus*, and *Bifidobacterium* and are included at about 5 billion to 20 billion colony forming units. See page 6 (lines 16-21), the passage between page 6 (line 28) and page 8 (line 25), page 13 (lines 22-28), and page 18 (lines 22-31).

Claim 3 sets forth exemplary embodiments of the carbohydrate ingredient of the nutritional food or nutritional product as supported by the specification at page 5 (lines 19-14), page 15 (lines 12-24), and Example 1 at pages 20 and 21.

Claim 4 sets forth exemplary embodiments of the fat ingredient of the nutritional food or nutritional product as supported by the specification at page 5 (lines 25-29), page 16 (lines 29-31), and Example 1 at pages 20 and 21.

Claim 5 sets forth exemplary embodiments of the protein ingredient of the nutritional food or nutritional product as supported by the specification at the paragraph spanning pages 5 and 6, page 17 (lines 9-17), and Example 1 at pages 20 and 21.

Claim 6 defines additional vitamins and minerals which can be included in the nutritional food or nutritional product. See page 6 (lines 9-11), page 15 (lines 1-10), and the paragraph spanning pages 17 and 18.

Claim 7 defines additional prebiotic ingredients which can be included in the nutritional food or nutritional product to favorably influence the growth of bacteria. Support for the inclusion of such prebiotic ingredients is found at page 6 (lines 4-9), page 6 (lines 25-27), page 15 (lines 10-11), and page 18 (lines 8-21) of the specification.

Claim 8 defines a particular embodiment of the nutritional food or nutritional product, whereby the composition is composed of at least one carbohydrate ingredient, at least one fat ingredient, at least one protein ingredient, at least one vitamin component, at least one mineral component, at least one prebiotic ingredient, and *Streptococcus thermophilus*. See the sentence spanning pages 4 and 5

of the specification. In particular, the probiotic bacterium, *Streptococcus thermophilus*, is selected for use in the nutritional food or nutritional product because of its propensity to hydrolyze nitrogenous wastes, wherein 5 billion to 20 billion colony forming units achieve a beneficial effect. See page 6 (lines 12-19), page 7 (lines 2-4), the paragraph spanning pages 8 and 9, page 11 (lines 11-16), page 13 (lines 22-28), and page 18 (lines 29-31). Furthermore, the fat ingredient is incorporated at about 2% to about 12% by weight of the total weight of the nutritional food or nutritional product to provide the added benefit of protecting the probiotic bacteria from moisture and maintaining viability. See page 5 (lines 25-29) and page 16 (lines 24-26). Moreover, a water activity of less than about 0.47 is specified to maintain viability of the probiotic bacteria and increase shelf-life of the nutritional food or nutritional product. See the paragraph spanning pages 12 and 13, page 14 (lines 14-24), and page 19 (lines 11-17).

Claim 9 defines a method for restoring and maintaining gastrointestinal health in a subject by administering to the subject a food or nutritional product of the invention. See the passage spanning page 9 (lines 4) and page 10 (line 8), the passage spanning page 10 (line 28) and page 12 (line 21), page 13 (lines 4-10), page 13 (lines 22-28), page 14 (lines 5-13), page 14 (lines 27-31) and page 20 (lines 1-14). To achieve the beneficial effect, the food or nutritional product is composed of *Streptococcus thermophilus* at a level of about 5 billion to 20 billion colony forming units and a prebiotic at about 2% to about 6% by weight, wherein the shelf-life and viability of the bacterium is preserved by having a water activity of less than about 0.47. Support for the probiotic *Streptococcus thermophilus* is found at page 6 (lines 12-19), page 7 (lines 2-4), the paragraph spanning pages 8 and 9, page 11 (lines 11-16), page 13 (lines 22-28), and page 18 (lines 29-31). Support for the prebiotic component is found at page 6 (lines 4-9), page 6 (lines 25-27), page 15 (lines 10-11), and page 18 (lines 8-

21) of the specification. Support for a water activity of less than about 0.47 is found at the paragraph spanning pages 12 and 13, page 14 (lines 14-24), and page 19 (lines 11-17).

Claim 10 defines a nutriceutical composition which alleviates the symptoms of uremia. Specifically, the composition is composed of a probiotic, a prebiotic, and *Streptococcus thermophilus* with pH stability and urea degrading activity, wherein said probiotic provides about 5 billion to 20 billion colony forming units of bacteria. See page 10, lines 10-27, of the specification. Probiotics, and their inclusion at about 5 billion to 20 billion colony forming units of bacteria, are characterized at page 6 (lines 16-21), the passage between page 6 (line 28) and page 8 (line 25), page 13 (lines 22-28), and page 18 (lines 22-31). Prebiotics are characterized at page 6 (lines 4-9), page 6 (lines 25-27), page 15 (lines 10-11), and page 18 (lines 8-21) of the specification. The benefits of *Streptococcus thermophilus* with pH stability and urea degrading activity are disclosed at the paragraph spanning pages 8 and 9.

VI. Grounds of Rejection to be Reviewed on Appeal

Whether claims 1-5, 7, 9, and 10 should stand rejected under 35 U.S.C. §103(a) as being unpatentable over Paul (U.S. Patent No. 5,744,134) in view of Cavalier-Vesely et al. (U.S. Patent No. 5,716,615), Brassart et al. (U.S. Patent No. 5,494,664) and/or Fridman (U.S. Patent No. 3,950,544).

Whether claims 1-10 should stand rejected under 35 U.S.C. §103(a) as being unpatentable over Paul (U.S. Patent No. 5,744,134) in view of Cavalier-Vesely et al. (U.S. Patent No. 5,716,615), Brassart et al. (U.S. Patent No. 5,494,664) and/or Fridman (U.S. Patent No. 3,950,544) in further view of Halpin-Dohnalek (U.S. Patent No. U.S. Patent No. 5,902,578).

VII. Arguments

A. The Rejection of Claims 1-5, 7, 9, and 10 Under 35 U.S.C. §103(a) Over Paul in View of Cavalier Vesely et al., Brassart et al. and/or Fridman Should Be Withdrawn

The Examiner asserts that Paul teaches compositions for restoring and maintaining GI health, comprising immunoglobulins (proteins), FOS (prebiotic), pectin (probiotic), beneficial human intestinal microorganism, wherein the composition is powdered. It is suggested that Paul teaches various *Lactobacillus* and *Bifidobcaterium* species and Streptococci. It is further suggested that Paul indicates that the composition can further include carbohydrates and lipids. The Examiner acknowledges that Paul does not teach that the bacteria are ammoniaphilic urea-degrading microorganisms with pH stability and urea degrading activity, the specific use of *S. thermophilus*, the claimed amounts of each of the component, or wherein the water activity is less than about 0.47. Despite the deficiencies in the teachings of Paul, the Examiner alleges that it would have been *prima facie* obvious for one of ordinary skill in the art to use the compositions of the Paul for restoring and maintaining gastrointestinal health, with the inclusion of the beneficial bacterium *S. thermophilus* since this bacterium was known to benefit the gastrointestinal tract, as taught by the Cavaliere Vesely et al., Brassart et al., and Fridman. Applicant respectfully submits that it is error to maintain this rejection based on the combined teachings of the cited references.

This rejection relies principally on Paul. As a whole, Paul teaches that an improvement and maintenance of gastrointestinal health can be achieved with an immunoglobulin composition comprising:

> "an immunoglobulin preparation containing immunoglobulins that bind and inactivate pathogenic microorganisms in the gastrointestinal tract and soluble dietary fiber that

> provides the typical advantages of dietary fiber and additionally is low in calories, does not affect blood glucose or insulin levels, and favors the growth of beneficial bacteria in the gastrointestinal tract while at the same time inhibiting the growth of potentially pathogenic or harmful microorganisms."

See column 3, lines 18-28. Paul teaches that the disclosed composition can *optionally* contain *0-20%* by weight of beneficial human intestinal bacteria (see column 13, lines 17-33), contain 5-10 parts by weight of lipid as an inert carrier (see column 5, lines 44-48) and be provided in the form of a powder *or liquid* (see the paragraph spanning columns 13 and 14).

Although the Examiner acknowledges that Paul is silent to *S. thermophilus* and the claimed amounts of each component or wherein the water content is less than about 4.7, the Examiner alleges that because Paul teaches that the composition of the mixture can be varied, "it would have been obvious to one of ordinary skill in the art to optimize the amounts of components and water content of the composition of the cited reference with a reasonable expectation for successfully obtaining the reference composition." See page 4 of the Final Rejection dated September 17, 2007. This general conclusion does not, however, constitute a factual basis for a rejection under 35 U.S.C. 103(a). *Cf. In re Warner*, 379 F.2d 1011, 1017, 154 USPQ 173, 178 (CCPA 1967), *cert. denied*, 389 U.S. 1057.

The Examiner bears the initial burden of presenting a *prima facie* case of obviousness. *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). In order to establish a *prima facie* case of obviousness, the Examiner must show that each and every limitation of the claim is described or suggested by the prior art or would have been obvious based on the knowledge of those of ordinary skill in the art. *In re Fine*, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988).

In actuality, Paul does not disclose any fact or notion for providing a high titer (*e.g.*, 5 to 20 billion CFU) of a viable

probiotic, in particular *S. thermophilus*, to the gastrointestinal tract. In fact, Paul explicitly indicates that

> "other ingredients are optional components of the invention. What is required is that the immunoglobulin composition contain an 'effective amount' of immunologically active immunoglobulins."

See column 5, lines 55-60. Accordingly, Paul provides no recognition that probiotics at particular titers are essential to achieve the result of restoring or maintaining gastrointestinal health. Consequently, Paul provides no teaching or suggestion of composition components which maintain a viable population of bacteria.

In contrast, Applicant has appreciated that a food or nutritional product containing a high titer of probiotic bacteria, ranging from about 5 to 20 billion CFU's, provides not only good gastrointestinal health and overall well-being, but also a greater propensity to hydrolyze toxic nitrogenous waste products thereby alleviating symptoms of uremia. See page 13, lines 23-28. Moreover, the claimed low-moisture nutritional food or nutritional products are an improvement over existing probiotic compositions, which are "prone to loss in viability due to their greater susceptibility to moisture, light, oxygen and heat," (see page 14, lines 15-24) in that the claimed compositions provide various elements which ensure a long shelf life and a viable population of probiotic bacteria. For example, the specification teaches that not only does the fat ingredient function as a lubricant, it also acts as a moisture barrier which has the "added benefit of protecting the probiotic bacteria from moisture, which is detrimental to maintaining a viable population of bacteria." See page 17, lines 4-8. In this regard, the claims clearly provide for a fat ingredient and further specify a water activity of less than about 0.47. See page 19, lines 11-17.

The courts have held that a particular parameter must first be recognized as a result-effective variable, *i.e.*, a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation. *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977). In so far as the composition of Paul can contain 0% of a beneficial human intestinal bacterium and can be in liquid form, it is not clear what results the Examiner thinks would be optimized by trying different bacteria, bacterial titers and water activity if Paul considers these elements optional. Paul simply does not consider probiotic bacteria (either their presence or titer) or water activity as critical variables for achieving the intended result of restoring or maintaining gastrointestinal health. Rather, immunoglobulins are the active ingredient of the compositions of Paul.

In addition, the secondary references of Cavaliere Vesely et al., Brassart et al. and Fridman fail to overcome the deficiencies of Paul. Cavaliere Vesely et al. teach compositions consisting of at least two lactic acid bacteria strains. Although *S. thermophilus* is mentioned by Cavaliere Vesely et al., nowhere does this patent teach or suggest 5 to 20 billion colony forming units of *S. thermophilus* in a composition. In fact, Cavaliere Vesely et al. specifically teach use of a much higher titer, namely 7×10^{11} colony forming units of bacteria, or at least 100 billion colony forming units. See column 3, lines 2-3. Furthermore, contrary to the Examiner's assertions regarding the teachings of Brassart et al., this patent only mentions preparation of yogurt with an undisclosed amount of this bacterium (see columns 3 and 4), with no teaching or suggestion of 5 to 20 billion colony forming units of *S. thermophilus* to enhance gastrointestinal health or alleviate symptoms of uremia. Instead, this patent teaches that *Bifidobacterium* strains exhibit a therapeutic benefit. See column 7. Moreover, contrary to the Examiner's assertions regarding

Fridman, this reference also fails to teach or suggest that *S. thermophilus* enhances gastrointestinal health or alleviates symptoms of uremia. The Fridman patent is directed to a method for producing yogurt from soy protein sources, wherein an undisclosed amount of a lactic acid culture, such as *S. thermophilus* or *L. bulgaricus,* is added to the sterile soymilk as starter. See column 3, lines 52-64. However, there is absolutely no discussion in this patent of a composition containing 5 to 20 billion colony forming units of *S. thermophilus* for use in enhancing gastrointestinal health or alleviating symptoms of uremia.

Given the teachings of the cited references, there would be simply no rationale for one skilled in the art to look to either Brassart et al. or Fridman for guidance in including *S. thermophilus* in the composition of Paul, because neither of these secondary references disclose any benefit of using *S. thermophilus* to enhance gastrointestinal health. Further, while Cavaliere Vesely et al. mention *S. thermophilus* as a bacterium for use in the treatment of gastrointestinal disorders, this reference teaches a higher titer of bacterium than claimed in the instant invention. Based on well-established principles of pharmacology and dose-response, there would be no rationale for one skilled in the art to include the *S. thermophilus* of Cavaliere Vesely et al. in the composition of Paul at the presently claimed dose, given that Cavaliere Vesely et al. suggest a higher dose.

Finally, none of the secondary references overcome the deficiency in the teachings of Paul with regard to fat content and water activity. The instant specification clearly teaches a water activity of less than 0.47 and the inclusion of a fat ingredient at 2% to 12% to protect probiotic bacteria from moisture. None of the secondary references discuss the criticality of these elements. Thus, whether alone or combined, the cited references fail to teach or suggest all the elements of the claimed invention.

Because the Examiner has not provided any compelling evidence of record to support the conclusion that it would have been obvious to optimize variables which are considered *optional* to the composition of Paul, and not even discussed by the secondary references, the Examiner has not met the initial burden of establishing why the prior art relied on would have led one of ordinary skill in this art to arrive at the claimed invention. Therefore, the cited references cannot be held to make the present invention obvious.

B. The Rejection of Claims 1-10 Under 35 U.S.C. §103(a) Over Paul in View of Cavalier Vesely et al., Brassart et al. and/or Fridman, and Further in View of Halpin-Dohnalek et al. Should Be Withdrawn

The Examiner suggests that it would have been *prima facie* obvious for one of ordinary skill in the art to alter the composition of Paul, adding *S. thermophilus* as taught by the Cavalier Vesely et al., Brassart et al. and/or Fridman, and then further modify the composition to include minerals and vitamins as taught by Halpin-Dohnalek et al. The Examiner expressly acknowledges that "[t]he references do not teach [] all of the ingredients together in a single composition in the claimed amounts, with the claimed water activity." See paragraph 3 at page 6 of the Final Rejection dated September 17, 2007. However, the Examiner alleges that it would have been obvious to one of ordinary skill in the art to combine the instant ingredients for their known benefit, as disclosed by the cited references, since each is well known in the art for their claimed purpose. Applicant respectfully submits that it is error to maintain this rejection based on the combined teachings of the cited references.

At the outset, Applicant respectfully submits that it is unclear how, on the one hand, the Examiner acknowledges that "[t]he references do not teach [] all of the ingredients together in a

single composition in the claimed amounts, with the claimed water activity," and on the other hand maintains that the claimed invention is obvious.

As in the above rejection, this rejection relies principally on Paul. As discussed *supra,* Paul fails to teach a composition containing 5 to 20 billion colony forming units of *S. thermophilus*, wherein said composition has a water activity of 0.47, for restoring or maintaining gastrointestinal health, or alleviating symptoms of uremia. Also as discussed *supra,* the combined teachings of Paul, Cavalier Vesely et al., Brassart et al. and/or Fridman fail to teach or suggest all the elements of the claimed invention, in particular the titer of bacteria and the water activity of the claimed compositions.

In this rejection, the Examiner has added Halpin-Dohnalek et al., suggesting that this reference further teaches compositions comprising minerals and vitamins, wherein said compositions provide 5 to 10 billion CFUs of *Lactobacillus reuteri*. However, Applicant respectfully submits that nowhere does this reference teach or suggest a composition containing 5 to 20 billion colony forming units of *S. thermophilus* for use in restoring or maintaining gastrointestinal health or alleviating symptoms of uremia. Thus, while compositions containing vitamins and minerals are suggested by Halpin-Dohnalek et al., it is respectfully submitted that this reference has little relevance to the claimed composition containing *S. thermophilus*.

In any event, like the teachings of the other secondary references, Halpin-Dohnalek et al. fail to compensate for the deficiencies in the teachings of the Paul. Nowhere does this reference teach or suggest the claimed amounts of ingredients, *e.g.,* the claimed fat content, or water activity, which are specified in the present claims to preserve bacterial titer. Indeed, Halpin-Dohnalek et al. teach at column 3, lines 42-46, a nutritional product composed of:

"protein, fat, carbohydrates, minerals, vitamins, trace elements and a probiotic system, said probiotic system comprising *Lactobacillus reuteri*, *Lactobaccilus acidophilus*, and *Bifidobacterium infantis*."

However, the only exemplification of a nutritional product is provided in Example 1, which teaches flavor packets containing a culture mix composed of 5 x 10^{10} CFU/g *Lactobacillus reuteri*, 5 x 10^{10} CFU/g *Lactobaccilus acidophilus*, and 6-7 x 10^{10} CFU/g *Bifidobacterium infantis* blended with either sucrose and cocoa powder; or sucrose, dextrose and vanilla flavor. In this regard, the bacterial component is the only ingredient of any composition disclosed by Halpin-Dohnalek et al. for which a specified amount is provided. In fact, there is absolutely no direction or guidance provided by this reference as to a starting point from which to optimize the components of the composition.

Thus, as in the above rejection, the combined teachings of the cited references applied in this rejection simply fail to teach or suggest all the elements of the claimed invention, in particular the titer of bacteria and the water activity of the claimed compositions. Therefore, the Examiner has not established a *prima facie* case of obvious under 35 U.S.C. 103(a).

Accordingly, reversal of the Examiner's rejections of claims 1-10 under 35 U.S.C. §103(a) is therefore respectfully requested.

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VIII. Claims Appendix

Claim 1 (previously presented): A nutritional food or nutritional product for maintaining or enhancing gastrointestinal health comprising *Streptococcus thermophilus*, at least one carbohydrate ingredient at about 47% to about 82% by weight of the total weight of the nutritional food or nutritional product, at least one fat ingredient at about 2% to about 12% by weight of the total weight of the nutritional food or nutritional product, and at least one protein ingredient at about 5% to about 80% by weight of the total weight of the nutritional food or nutritional product, wherein the water activity of the nutritional food or nutritional product is less than about 0.47, and wherein said nutritional food or nutritional product provides about 5 billion to 20 billion colony forming units of said *Streptococcus thermophilus* bacteria.

Claim 2 (previously presented): The nutritional food or nutritional product of claim 1 further comprising at least one probiotic bacteria selected from the group consisting of *Lactobacillus acidophilus, L. bulgaricus, L. casei, L. rhamnosus, L. fermentum, L. salivaroes, L. brevis, L. plantarum, L. ruteri, Bacillus sporogenes, Bifidobacterium adolescentis, B. infantis, B. longum, B. thermophilum* or *B. bifidum* and wherein said nutritional food or nutritional product provides about 5 billion to 20 billion colony forming units of said at least one probiotic bacteria.

Claim 3 (previously presented): The nutritional food or nutritional product of claim 1 wherein said at least one carbohydrate ingredient is dextrose, sucrose, fructose, lactose, maltose, galactose, sugar alcohols, invert sugar syrups, brown sugar, corn syrup, corn syrup solids, honey, molasses, maple syrup, fruit juices, stevia, or an artificial sweetener.

Claim 4 (original): The nutritional food or nutritional product of claim 1 wherein said at least one fat ingredient is olive oil, canola oil, palm oil, coconut oil, sunflower oil, peanut oil, vegetable oil, lecithin, fish oil, cotton seed oil, soybean oil, lard, monoglycerides, diglycerides, butter, margarine, and other animal, vegetable, and marine fats, or milk fats.

Claim 5 (original): The nutritional food or nutritional product of claim 1 wherein at least one protein ingredient is cereal proteins, milk proteins, egg proteins, animal proteins, vegetable proteins, whey protein, bean proteins, lactalbumin-casein co-precipitate, calcium caseinate, sodium caseinate, purified or refined grades of casein and soy proteins, or peanuts.

Claim 6 (original): The nutritional food or nutritional product of claim 1 further comprising at least one vitamin component and at least one mineral component.

Claim 7 (previously presented): The nutritional food or nutritional product of claim 1 further comprising at least one prebiotic ingredient, wherein the at least one prebiotic ingredient is a fructo-oligosaccharide, a galacto-oligosaccharide, a soy-oligosaccharide, a xylo-oligosaccharide, a isomalto-oligosaccharides, Jerusalem artichoke flour, rolled oats, banana fiber, a pectin and pectic polysaccharide, a mannan, a pentosan, a beta-glucan, a rabinan or a galactan.

Claim 8 (previously presented): A nutritional food or nutritional product for maintaining or enhancing gastrointestinal health, comprising at least one carbohydrate ingredient, at least one fat ingredient, at least one protein ingredient, at least one vitamin component, at least one mineral component, at least one prebiotic ingredient, and *Streptococcus thermophilus*, wherein said

S. thermophilus has a propensity to hydrolyze nitrogenous waste products and the at least one fat ingredient is about 2% to about 12% by weight of the total weight of the nutritional food or nutritional product, wherein the water activity of the nutritional food or nutritional product is less than about 0.47, and further wherein said nutritional food or nutritional product provides about 5 billion to 20 billion colony forming units of said *Streptococcus thermophilus* bacteria.

Claim 9 (previously presented): A method of restoring and maintaining gastrointestinal health comprising administering to a subject at least one food or nutritional product comprising an effective amount of *Streptococcus thermophilus* and about 2% to about 6% by weight of a prebiotic, wherein the water activity of the nutritional food or nutritional product is less than about 0.47, and wherein said *Streptococcus thermophilus* bacteria is present at a level of about 5 billion to 20 billion colony forming units.

Claim 10 (previously presented): A nutriceutical composition to alleviate the symptoms of uremia comprising a composition of a probiotic, a prebiotic, and *Streptococcus thermophilus* with pH stability and urea degrading activity, wherein said probiotic provides about 5 billion to 20 billion colony forming units of bacteria.

Claim 11 (canceled).

IX. Evidence Appendix

No evidence is being provided.

X. Related Proceedings Appendix

There are no related proceedings.